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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,595	08/22/2003	Stanley W. Huth	14628/301681	9800

33357 7590 01/04/2007  
ADVANCED MEDICAL OPTICS, INC.  
1700 E. ST. ANDREW PLACE  
SANTA ANA, CA 92705

EXAMINER
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MARTIN, PAUL C

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/646,595	HUTH ET AL.
	Examiner	Art Unit
	Paul C. Martin	1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2 and 4-10 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2 and 4-10 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_.

**DETAILED ACTION**

Claims 1, 2 and 4-10 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Objections***

Claim 4 is objected to because of the following informalities: Claims 4 seems to be dependent upon cancelled Claim 3 . Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The rejection of 1, 2 and 4-10 under 35 U.S.C. 112, 1<sup>st</sup> paragraph as not being enabled for the full scope of the claims has been withdrawn due to the Applicant's amendment to the claims filed 09/28/06.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "the intermediate" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

Claims 1, 4 and 6-8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Kovacs-Hadady *et al.* (1998).

This rejection is maintained for reasons of record set forth in the paper Action mailed 05/19/06, repeated below (slightly altered to take into consideration Applicant's amendment to the Claims).

Kovacs-Hadady *et al.* teaches a cell-free system for determining the presence of the preservative/antimicrobial Benzalkonium Chloride (BC), wherein the probe Eosin-Y (a dye molecule) is used to detect the presence of BC based on absorbance readings from a light spectroscope to detect the ionic complex formed by the cationic BC and Eosin Y (Pg. 735, Column 1, Lines 35-40 and Column 2, Lines 1-17 and Fig. 1).

Kovacs-Hadady *et al.* teaches a test vessel for performing the assay that includes a multi-purpose buffer solution comprising BC (Pg. 735, Column 1, Lines 1-12)

It is inherent in the method of Kovacs-Hadady *et al.* that the antimicrobial benzalkonium chloride is effective against at least one of *S. marcescens*, *S. aureus*, *P. aeruginosa*, *C. albicans* and *F. solani*, the light source for the spectrophotometer emits light radiation which inherently includes a band of wavelengths, and the detector measures the absorption resulting from the formation of a complex of the BC and Eosin Y. Data correlating the spectral change with a reduction in the number of live microbes when treated with the agent and a calibration graph including data, are not parts of the system as claimed, constituting mental steps or calculations which do not materially change the system as claimed.

Although Kovacs-Hadady did not explicitly teach a method for predicting the antimicrobial activity of an agent, the interaction between the BC and the eosin is inherently analogous to the interaction which would occur between the BC and a microbial cell membrane, since BC is known in the art to disrupt or destroy microbial cell membranes upon contact.

The MPEP states: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Kovacs-Hadady teaches the use of a calibration graph of absorbencies wherein the activity of the eosin-BC interaction can be analyzed in Fig. 1a, wherein the activity of the interaction between eosin-BC was plotted and adjusted for blank/control absorbance.

#### ***Response to Arguments***

The Applicant's arguments filed 09/28/06 have been fully considered but they are not deemed to be persuasive.

The Applicant argues that Kovacs-Hadady *et al.* doesn't teach, suggest or motivate one of ordinary skill in the art to "data correlating the spectral change with a reduction in the number of live microbes treated with the agent", and that the reference is silent with regard to any correlation between spectral changes in BC-dye complexes in the solution with incidence of a particular microbe when treated with BC (Remarks, Pg. 5, Lines 17-25).

The Applicants arguments are not found to be persuasive for the following reasons, from instant Claim 1 there is no indication that any live microbes are included in the cell free system as described, the only components seem to be a probe molecule, an agent, a source of light radiation and a detector. Therefore, any "data correlating the spectral change with a reduction in the number of live microbes treated with the agent" or "...correlation between spectral changes in BC-dye complexe's in the solution with incidence of a particular microbe when treated with BC" , would be a mental step or calculation on the part of the Applicant which does not materially change or affect the system as claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 6-8 and 10 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs-Hadady *et al.* (1998) in view of Park *et al.* (US 6,316,669 B1).

The teachings of Kovacs-Hadady *et al.* were discussed above.

Kovacs-Hadady *et al.* does not teach wherein the agent is not BC, or wherein the agent is polymeric.

Park *et al.* teaches the use of the polymeric antimicrobial compound Polyhexamethylene biguanide (PHMB) (Column 1, Lines 59-66).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell-free system for determining the presence of the preservative/antimicrobial Benzalkonium Chloride (BC), wherein the probe Eosin-Y (a dye molecule) is used to detect the presence of BC based on absorbance readings from a light spectroscope to detect the ionic complex formed by the cationic BC and Eosin Y as taught by Kovacs-Hadady *et al.* above with the use of the polymeric antimicrobial compound PHMB as taught by Park *et al.* because one of ordinary skill in the art would have recognized PHMB as a functional variation of BC. One of ordinary skill in the art would have been motivated to make this modification because the use of alternatives and functional equivalent techniques would have been desirable to those of ordinary skill in the art based upon the economics and availability of compounds. There would have been a reasonable expectation in making this substitution because both compounds are known antimicrobials and used as preservatives in ocular preparations.

Claims 1 and 4-10 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs-Hadady *et al.* (1998) in view of Horonick *et al.* (US 3,678,151).

The teachings of Kovacs-Hadady *et al.* were discussed above.

Kovacs-Hadady *et al.* does not teach wherein the probe molecule is effective to dye Gram positive organisms or wherein the detector is a human eye.

Horonick *et al.* teaches the use of Gram positive stains (such as Crystal Violet) for use in staining bacteria and detecting the stain with the human eye (Column 5, Lines 3-17) and the use of Eosin Y as a biological stain (Column 3, Lines 50-53).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the cell-free system for determining the presence of the preservative/antimicrobial Benzalkonium Chloride (BC), wherein the probe Eosin-Y (a dye molecule) is used to detect the presence of BC based on absorbance readings from a light spectroscope to detect the ionic complex formed by the cationic BC and Eosin Y as taught by Kovacs-Hadady *et al.* above with the use of other organic dye probe molecules such as Crystal Violet because one of ordinary skill in the art would have recognized that Crystal Violet is an obvious functional variation of the organic dye probe Eosin Y.

One of ordinary skill in the art would have recognized that certain organic dyes are capable of being visually detected when reacting with a substrate, such as the stain disclosed by Horonick *et al.* above. One of ordinary skill in the art would have been motivated to make this modification because the use of alternatives and functional equivalent techniques would have been desirable to those of ordinary skill in the art based upon the economics and availability of compounds. One of ordinary skill in the art would have been motivated to use the human eye as a means of detecting the interaction of Crystal Violet with the agent because the dye is known to be optically visible to the human eye. There would have been a reasonable expectation of success in making this substitution because Crystal Violet and Eosin Y are known staining agents in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1657

12/22/06



JON WEBER  
SUPERVISORY PATENT EXAMINER